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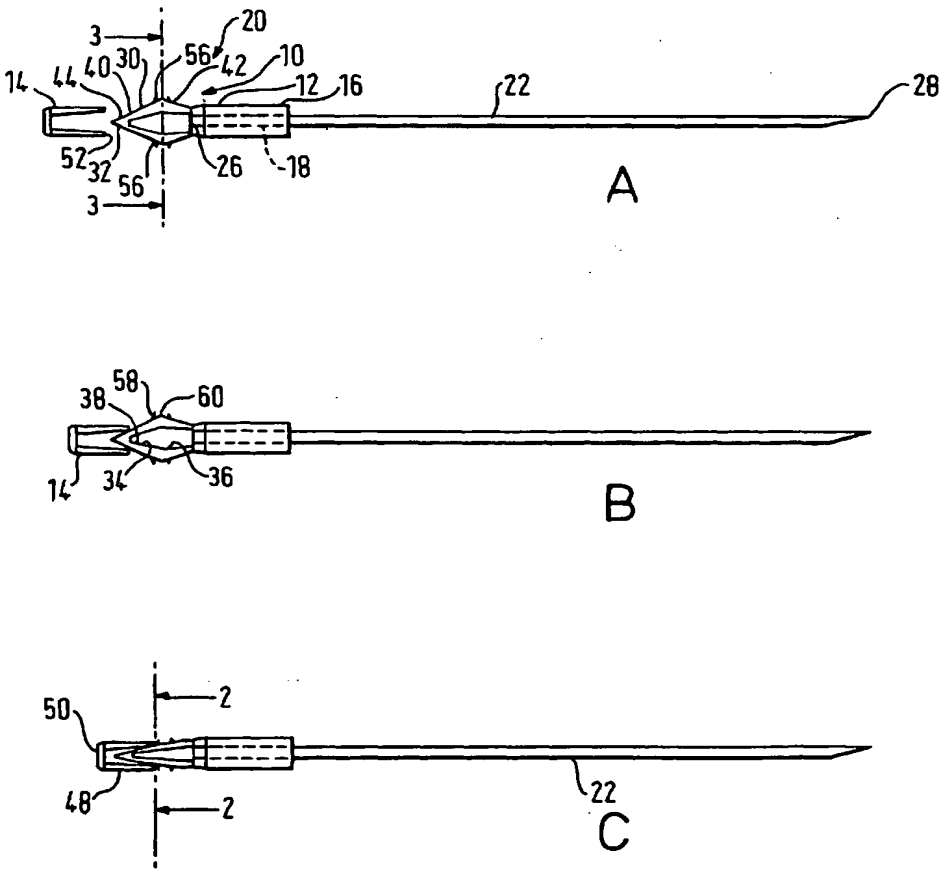

(57) Abstract: A locking mechanism (10) for a medical sharp device such as a syringe assembly (62) includes a retainer part (12) for retaining a hypodermic needle (22), and a connector part (14). The retainer part includes lugs (46) for engagement with a recess (82) formed in a neck (70) of the syringe assembly. When a plunger (72) of the syringe assembly is pushed fully forwards, the lugs (56) of the retainer part (12) engage behind a ledge (54) of the connector part (14) and the lugs (46) disengage from the recess (82). The plunger (72) may then be retracted, pulling the needle (22) into the barrel (64) of the assembly. The neck portion may be eccentrically mounted on the barrel and means (116, 118) may be provided for preventing rotation of the plunger (72) in the barrel (64).

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MEDICAL DEVICE AND LOCKING MECHANISM THEREFOR

The present invention relates to locking mechanisms for controlling engagement between parts moveable relative to one another in medical sharp devices. The invention also relates to medical devices, such as hypodermic needle devices including syringe assemblies, cannulas and catheters including butterfly catheters, which incorporate such mechanisms. The invention also relates to hypodermic needle assemblies.

There is a need for non-reusable safe medical sharp devices such as hypodermic syringes. It is known that the reuse of hypodermic needle devices is unsafe practice. There is a risk to patients and others of infection. The improper disposal of used syringes and needles also presents a risk to healthcare workers and others. It is also known that needlestick incidents are undesirable for both healthcare workers and patients since infections such as HIV, Hepatitis B and C, Ebola fever, Lassa fever, Syphilis, Tuberculosis, Herpes, Brucellosis and Streptococcal conditions may be accidentally transmitted during needlestick incidents.

Furthermore, it is now believed that the BSE and/or vCJD protein or proteins may be resistant to sterilisation processes such that the problems and dangers of reuse of human medicine sharp devices are also applicable in veterinary medicine.

Some attempts have been made to address the above problems by providing what are known as "safety" syringes which are supposed to be non-usable once they have been used once. One type of known "safety" syringe includes a spring which is adapted to force a hypodermic needle backwards into a retracted position inside a barrel of a hypodermic syringe. A problem with this type of apparatus is that the spring can cause the

hypodermic needle to spring back suddenly out of the patient, causing discomfort to the patient especially when the operator of the device is applying a slight bending moment to the needle at the time of the sudden needle retraction by the spring. Furthermore, the spring can be very expensive, since the steel used can be required by medical standards to remain sterile for a number of years and thus very expensive steel must be employed.

Another type of known "safety" syringe include an outer barrel which is sprung forwards by a spring along the main syringe barrel and over the needle once a plunger of the syringe has been depressed. The mechanism is very complicated and expensive due to the need for the spring and additional sheath barrel.

Another type of known "safety" syringe, as described in US-A-5431631, includes a mushroom-shaped locking device for locking the front of a hypodermic needle assembly's plunger to a needle retainer once the plunger has been fully depressed. The plunger may then be manually retracted, overcoming the rather complicated engagement at a forward location between a bead on the retainer part and the barrel. This arrangement is not only complicated and expensive incorporating a number of parts, but the patient may feel an uncomfortable sensation as the mushroom-shaped part suddenly engages. Furthermore, the needle is spaced a substantial distance in front of the end of plunger movement along the barrel meaning that, when the device is used for injection purposes, substantial volume of the material to be injected is wasted.

Known types of "safety" syringe are very expensive being up to ten times more costly than "standard" syringes of the reusable type. Although the use of reusable syringes is mandatory in some jurisdictions, the cost of

known "safety" syringes is such that it is proving difficult to comply with this mandatory requirement.

Known hypodermic needle assemblies use glue to retain and seal the steel needle of the assembly in a retainer part therefor. The use of glue is somewhat unreliable and has a cost implication.

Furthermore, in known systems it is often not possible to change needles before use of an assembly. In cases in which this is possible, there is often a substantial non-displaced volume of fluid in front of a plunger of the device when the plunger is fully depressed and this means that a substantial amount of fluid is wasted when using the device for injection purposes.

The present invention aims to alleviate at least some of the problems of the prior art.

According to a first aspect of the present invention there is provided a locking mechanism as set out in claim 1. This locking mechanism is highly advantageous since it is very simple and can be incorporated in a cost-effective manner into various types of medical device, such as hypodermic syringes for injection or extraction of material from patients in a cost-effective manner. Furthermore, in preferred embodiments of the invention, the locking mechanism can be incorporated to allow one actuation of the device, followed by retraction of the medical sharp device. The medical sharp device will normally comprise a needle, but may comprise other types of sharp device, such as a knife or other cutting instrument.

A number of preferred features of the locking mechanism will now be described.

The first formation may comprise a lug and the second formation may comprise a recess or cavity formed in the body. A pair of said lugs may be

provided on opposite sides of the retainer part and the recess may comprise an annular recess in the body part.

Preferably, the retainer part includes a flexible leg, the first formation being located on the leg, the connector part being adapted to flex the leg on engagement with the retainer part to move the first formation relative to the body part. Most preferably, the said retainer part includes at least two said legs, the connector part being adapted to move the said legs towards one another on engagement with the retainer part. Therefore, before engagement of the retainer part by the connector part, the legs may be outwardly biased for engagement with the body part for holding the retainer part firmly relative to the body part, but on engagement of the retainer part by the connector part, the connector part may move the said legs for reducing the effectiveness of engagement between the retainer part and the body part, and the connector part may then be moved for disengaging the retainer part from the body part.

The connector part may be linearly moveable to engage the retainer part, the connector part, on engagement with the retainer part, causing movement of at least one said leg in a direction generally perpendicular to the said direction of movement of the connector part.

The said legs may be mutually joined at respective ends thereof. Preferably, the legs form a diamond shape when their respective ends are joined. Accordingly, the structure formed by the legs may be relatively resilient, such that, when the legs are engaged with the body part, the engagement is relatively effective.

The body part may take various forms but will usually be an item fixed to or part of a main body of the medical device. Thus the body part may comprise, for example, a central tubular body part of a catheter e.g. a

butterfly catheter or cannula, or may comprise a portion of a barrel part of a hypodermic needle assembly, such as a neck portion of such an assembly, especially when the barrel comprises a main cylindrical part joined at a front end thereof by a tapered or conical shoulder to a neck.

The body part may comprise an element releasably coupled to a main body of a medical device, for example, a releasable needle retention hub in the case of a hypodermic needle assembly.

Preferably, each said leg has an inner surface and an outer surface, the outer surface being longer than the inner surface. It is believed that this construction has the advantage that the leg will be relatively resilient against bending in response to engagement thereof by the connector part. The inner surface of the leg may be relatively flat and the outer surface may be curved or outwardly convex, in order to provide the longer configuration of the outer surface relative to the inner surface.

The connector part preferably comprises a generally cylindrical element. The connector part may include an internal bore into which at least part of the retainer part is insertable. The connector part preferably includes an annular ledge at an entrance to the bore. The retainer part preferably includes at least one connector protrusion for engagement behind the annular ledge. Preferably, two said connector protrusions are provided, the connector protrusions being asymmetrically configured for asymmetrically configured for asymmetrically engaging the annular ledge. Thus, the engagement between the connector protrusions and the annular ledge may be such that the connector part provides a tilting force on the retainer part, and this may be highly beneficial when the retainer part is used to retain a hypodermic needle, so that in preferred embodiments the needle may be retracted inside a barrel of a hypodermic syringe and then automatically

tilted by the locking mechanism, e.g. so that it cannot be reused.

In a preferred embodiment, the retainer part is adapted to retain a hypodermic needle, the retainer part including an elongate bore passing therethrough, the bore being engageable with a cylindrical outer surface of a needle. Preferably, the elongate bore includes internal ribs, such as circumferentially extending ribs, for sealingly gripping a needle, for example, with a push-fit and/or interference fit. Accordingly, it is not necessary to use glue to mount the needle.

Accordingly, according to a second aspect of the present invention there is provided a hypodermic needle assembly as set out in claim 23. The substantial advantage of a push fit sealing engagement between the needle and the retainer for the needle is that glue is not needed. The push-fit may alternatively or additionally comprise an interference fit (e.g. a push interference fit or a shrink interference fit in which the retainer part is shrunk on to the needle. Therefore, the unreliability and cost of using glue may be avoided.

The bore preferably includes a series of ribs for sealingly engaging an outer surface of the needle. The ribs are preferably circumferentially extending ribs. This has the advantage that the needle is gripped at a number of locations spaced axially therealong, and the series of ribs provide a series of sealing engagements between the needle and retainer such that the sealing between the needle and retainer is relatively effective.

A further aspect of the invention provides a hypodermic needle assembly as set out in claim 26. Various optional features are mentioned in claims 27 to 36.

A further aspect of the invention provides a medical device as set out in claim 37.

A further aspect of the invention provides a medical device as set out in claim 38. Preferably, the device comprises a hypodermic needle device. The device may comprise a catheter (e.g. a butterfly catheter) or cannula or other hypodermic needle device. The medical device may comprise a hypodermic syringe. In this case, the retainer part may be adapted to retain a hypodermic needle of the device and the connector part may be mounted on a plunger of the syringe. The hypodermic syringe may be used for injecting or extracting material such as fluid to or from a patient.

Preferably, the syringe includes a barrel, the barrel having a main cylindrical part, a conical or tapered shoulder portion at a forward end of the main cylindrical part, and a neck portion in front of the shoulder portion, the said second formation of the locking mechanism being formed internally in the neck portion of the barrel. Preferably, the neck portion of the barrel includes a front end and a rear end thereof, the rear end being adjacent a front end of the shoulder portion, the second formation of the locking mechanism comprising an annular internal recess or cavity formed at the rear end of the neck portion. It will therefore be appreciated that an advantage of the location of the second formation at the rear end of the neck portion is that the hypodermic needle may be located at least partially inside the neck portion with the adjacent end of the hypodermic needle located inside the neck portion and preferably no more than 25% or 50% of the way along the neck portion from the rear end thereof, such that, when used for injecting fluid, a small amount of fluid/material will be wasted.

Preferably, the device includes a hub part for releasably sealably retaining the retainer part on the barrel of the syringe. Thus, the retainer part and needle may be removed from the device and replaced, such as with a retainer and needle of different configuration, such as when a different

needle diameter or gauge is required. The hub may include a stop surface for preventing forward movement of the retainer part relative to the barrel. Thus, when the plunger is pushed forwards, the hub maintains the retainer part and needle in position, but once the connector part has engaged the retainer part and altered the engagement between the retainer part and the body part, e.g. the preferred annular recess in the neck portion of the barrel, the plunger may be retracted such that the connector part may pull the retainer part and needle into the barrel. The plunger preferably includes a weak region, such that after use, the plunger may, if desired, be snapped to assist in preventing further use of the device. Furthermore, the plunger preferably includes a jam mechanism for preventing removal of the used hypodermic needle from the barrel.

A further aspect of the invention provides a locking mechanism for a medical device comprising a retainer part for retaining medical sharp devices, the retainer part including at least one connector portion thereof adapted for engagement against a body part of a medical sharp device, and a connector part, the connector part being adapted for movement to engage the connector portion for connection therewith, movement of the connector part once connected to the connector portion causing movement of the retainer part.

Preferably, the connector portion comprising a flexible leg.

Preferably, two said flexible legs are provided extending generally parallel to one another, engagement of the connector part with the legs causing the legs to move towards one another.

Preferably, the legs are joined together in a diamond shape preferably having a general V-shaped end portion joined to an inwardly tapering portion adjacent a needle retaining body of the retainer.

Preferably, each said leg includes a lug adapted for engagement with a recess formed in the body part, the movement of the connector part to engage the leg causing a reduction in the force of engagement between the lug and recess.

Preferably, the connector part includes a generally cylindrical bore, the bore being adapted to receive each said leg on engagement of the connector part therewith.

Preferably, the bore includes an annular ledge at an entrance thereto and each said leg includes a connector projection adapted to ride over and lock past the ledge on insertion into the bore.

Another aspect of the invention is set out in claim 53. Various optional features are mentioned in claims 54 to 56.

The present invention may be carried out in various ways and a preferred embodiment of a locking mechanism and its incorporation in a preferred hypodermic syringe assembly and preferred butterfly catheter in accordance with the invention will now be described by way of example with reference to the accompanying drawings, in which:

Figs. 1A to 1C are various schematic side views of a preferred embodiment of a locking mechanism in accordance with the present invention, a preferred retainer part thereof retaining a hypodermic needle;

Fig. 2 is a schematic sectional view in the direction 2 shown in Fig. 1C;

Fig. 3 is a schematic sectional view in the direction 3 shown in Fig. 1A;

Figs. 4A to 4F are schematic side views showing the operation of the preferred locking mechanism of Figs. 1A to 1C and 2 and 4, incorporated in a preferred hypodermic needle assembly;

Fig. 5 shows a schematic side view of an alternate hub for the assembly of Figs. 4A to 4F;

Figs. 6A to 6D show various schematic side views of the locking mechanism of Figs. 1A to 1C when incorporated in a preferred butterfly catheter having a slightly shorter needle than the needle shown in Figs. 1A to 1C;

Fig. 7 is an enlarged side view of the retainer part and connector part shown in Figs. 1 to 4;

Fig. 8 is a view corresponding to Fig. 7, in the direction of the arrow marked 8 in Fig. 7;

Fig. 9 is a view corresponding to Fig. 8, in the direction "9" in Fig. 8 but excluding the connector part 14;

Fig. 10 is an end view of an embodiment of a syringe assembly having an eccentrically located neck portion;

Fig. 11 is a further embodiment of a hypodermic needle assembly, in which the section of a barrel of the assembly is non-circular; and

Fig. 12 is a schematic side view of each of the assemblies shown in Figs. 10 and 11.

A preferred locking mechanism 10 in accordance with a preferred embodiment of the present invention is shown in Figs. 1A to 1C, Fig. 2 and Fig. 3. The locking mechanism 10 comprises a retainer part 12 and a connector part 14. The retainer part 12 includes a body part 16 or a generally cylindrical needle retainer 16 having an elongate bore 18 formed therethrough. An adjacent end 20 of a hypodermic needle 22 has a circular entrance aperture 24 thereto flush with one end 26 of the bore 18. The other, distal end 28 of the needle 22 is sharp, and it will be understood that the needle 22 has an internal bore (or lumen) (not shown) formed therealong

for the transmission of material, such as medicine being injected to, or blood or other bodily fluids being extracted from a patient.

The retainer part 12 includes a pair of resilient legs 30 formed integrally with the cylindrical needle retainer 16, the legs 30 being mutually joined at one end 32 thereof. The legs 32 form a diamond-shaped section, consisting of V-shape end portion 31 adjacent an inwardly tapered portion 33 adjacent the needle retainer 16. The joining of the legs in a "V" provides additional resilience against squashing thereof by the connector part 14 as will be described below. Furthermore, each leg 30 includes a generally flat inner surface 34, formed by two flat surfaces 36,38 and a generally concave or curved outer surface 40, formed by two surfaces 42,44. The arrangement of flat 34,36,38 surfaces and concave/curved 40,42,44 surfaces, provides additional resilience for the legs 30 against movement towards one another.

Figs. 7 to 9 show enlarged views of the retainer 12 and connector 14. It will be appreciated that the connector 14 is cylindrical and Figs. 7 and 8 thus show a schematic section through this part.

As shown in Fig. 3, each leg 30 includes a formation 46 formed thereon in the form of a lug 46 extending generally transverse to the longitudinal direction of the needle 22.

As shown in Fig. 4B and 7 to 9 the retainer 12 may include an annular seal 51 formed adjacent a rear end thereof (omitted for clarity in other drawings) for sealing inside the neck of the syringe. This seal is located well inside the neck portion as is the rear entrance to the needle and this means that almost no fluid is wasted as excess when injecting.

The seal 51 may be replaced with alternative sealing means in other embodiments

The connector part 14 of the locking mechanism comprises a cup-

shaped element 48 having one end 50 which may be closed (or in other embodiments open) and a second end 52 which is open but includes an annular ledge 54 which is inwardly extending at an entrance to the cup. The legs 30, in addition to the lugs 46 (which are symmetrically located about the longitudinal axis of the hypodermic needle), includes two further lugs 56 which are located somewhat asymmetrically about the axis of the needle 22. The further lugs 56 are spaced further along the legs 30 from the needle retainer part 16 of the retainer part 12 than the lugs 46.

As shown in the sequence of Figs. 1A to 1C, the connector part 14 may be moved linearly towards the retainer part 12 until the inner edge 58 of the ledge 54 engages the legs 30 as shown in Fig. 1B. Further movement of the connector part 14 linearly in the axial longitudinal direction of the needle 22 causes the legs 30 to be transversely moved towards one another. Eventually, the ledge 54 rides over the further lugs 56, the further lugs 56 having chamfered surfaces 58 allowing the ledge 54 to ride over the lugs 56, but transverse flat surfaces 60 (perpendicular to the needle axis) opposing the chamfered surfaces 58, the flat transverse surfaces 60 thus preventing removal of the connector part 14 from the retainer part 12, once the ledge 54 has ridden over the lugs 56 to place the connector part 14 and retainer part 12 in the engaged configuration shown in Fig. 1C.

Thus, as shown in Figs. 4A to 4F, the preferred locking mechanism 10 may be incorporated in a preferred syringe assembly 62 in accordance with a preferred embodiment of the present invention.

As best shown in Figs. 4A to 4F, the needle 22 is a push-fit in the needle retainer 16, the needle retainer including a series of circumferential ribs on the internal bore 18 thereof, e.g. about ten spaced circumferentially extending ribs, the ribs 18 compressing against the needle 22 in order to hold

the needle 22 in position and provide a good seal. Accordingly, it is not necessary to use glue to attach the needle 22.

The syringe assembly 62 includes a barrel 64 having a main cylindrical part 66, a conical shoulder 68 and a cylindrical neck 72. The assembly 62 also has a plunger 72 having a stem 74 for operating a piston 76, the piston 76 being sealed against the barrel main cylindrical part 66 with an O ring 78. The neck 70 of the barrel 64 includes at a rear end 80 thereof an internal annular recess or cavity 82. The retainer part 12 holding the needle 22 may be connected to a hub 84 (or the alternative hub 84 shown in Fig. 5) and, later, the retainer part 12 may be pushed into the neck 70 of the barrel 64 to the configuration shown in Fig. 4A in which the lugs 46 are resiliently engaged in the internal annular recess 82 at the rear end 80 of the neck 70. The resilience of the lugs 46 and the legs 30 is such that when the plunger 72 is drawn backwards to draw material such as a vaccine, medicine or bodily material such as blood into the barrel 64, the retainer part 12 and hypodermic needle 22 are retained in position, with transverse surfaces 61 of lugs 46 engaging in the recess 82. Furthermore, the hub 84 is provided with a stop element/stop surface 86 for preventing forward movement of the needle 22 when the plunger 72 is pushed forwards. It will be appreciated that there is a gap 86 between the legs 30 such that fluid may flow from the barrel, through the gap 86 into the entrance aperture 24 and along the needle 22 or, of course, in the opposite direction.

When the syringe assembly 62 is used to give an injection, the plunger is pushed forwards, for example, from the position shown in Fig. 4A to the position shown in Fig. 4B and then to the position shown in Fig. 4C. As the plunger 72 approaches the configuration shown in Fig. 4C, it will be appreciated that the locking mechanism 10 adopts first the configuration

shown in Fig. 1A, then the configuration shown in Fig. 1B and then the configuration shown in Fig. 1C which is the same as the configuration shown in Fig. 4C. As the connector part 14 of the locking mechanism 10 moves along the legs 30, it squashes the legs 30 towards one another and, in doing so, the lugs 46 disengage from the internal annular recess 82 in the neck portion 70 of the barrel 64 and, the ledge 54 of the connector part 14 rides over the lugs 56. Accordingly, when the plunger 72 is pulled backwards to the position shown in Fig. 4B, the connector part 14 pulls the retainer part 12 and needle 22 with it. The needle 22 maintains a generally longitudinally configuration until the end 28 passes through the neck portion 70 and along the inside of the shoulder 68 of the barrel. Due to the thin flat nature of the legs 30 and the asymmetric configuration of the lugs 56, together with the inward squashing forces provided to the legs 30 by the ledge 54, the connector part 14 provides a tilting force on the retainer part 12 and needle 22, such that the needle tilts by about 5° as shown in Fig. 4E and Fig. 4F, such that it is then not possible to push the needle forwards out through the neck 70 for reuse. Furthermore, the rear end 88 of the barrel 64 includes a slight constriction 90 and the stem 74 includes a jamming element 92 shown for the purposes of clarity schematically only and only in Fig. 4F, which prevents the stem 74 from being fully removed from the barrel 64. Thus, not only is the needle 22 safely enclosed in the barrel 64 after use, but the needle 22 also cannot be removed for attempted reuse on another apparatus. As indicated in Fig. 4F, a weak spot 94 on the stem 74 of the plunger 72 conveniently allows the plunger to be snapped for showing even the most inexperienced user or persistent attempted reuser of needles 22 that the needle 22 has been used and is now inoperative and should not be reused.

Figs. 6A to 6D show a development on the apparatus shown in Figs.

4A to 4F in which the preferred locking mechanism 10 of Fig. 1A to 1C, 2 and 3 is instead incorporated in a butterfly catheter 100, this apparatus including a shorter needle 22 . The locking mechanism 10 works on a similar principle in Fig. 6A to 6D and the connector part 14 has an open end 102 which may be connected to a fluid tube 104 for various purposes such as provision of a drip (not shown). After use, the needle 22 may be retracted into the butterfly device body 104 and a slightly shorter needle retainer 16 of the retainer part 12 and the retainer 16 shown in Figs. 1 to 4 may be pulled longitudinally behind a tube section 106 of the body 104 such that the needle retainer 16 cannot be pushed inside the tube 106 again and the needle 22 therefore cannot be pushed forwards out of the body 104 for reuse.

The embodiments of the invention, it is envisaged, may have application in the fields of both human and veterinary medicine.

It will be appreciated from the above that embodiments of the invention may provide a hypodermic medical device such as a syringe assembly in which a needle is secured, without glue or adhesive, in its optimal position for use in injecting or extracting. The needle may be subsequently locked into the inner end of a plunger or piston to permit withdrawal wholly into the barrel of the syringe or the body of the device. The complete assembly may then be discarded without fear of accidental infection through needlestick. The device/syringe is thus rendered safe and cannot be refilled or reused and it can be disposed of safely. The device may be produced in quantity at a competitive price. The retainer part 12 which may also be considered a central hub combines a central channel for transmission of fluid being injected or extracted with a ribbed internal contour that engages with the surface of the needle. This internal locking mechanism shows that the needle is firmly secured in a base that is in turn

married with forward end or neck of the syringe barrel. The outer surface of the central hub or retainer part is contoured such that the combined central hubs/retainer and needle assembly can be easily and firmly attached to the neck of the syringe barrel readying the syringe ready for use. The syringe may then be filled in the normal way for injection by drawing back the plunger, thus drawing injectable fluid into the barrel. The union of the needle hub and barrel of course forms an effective seal to prevent leakage and appropriate sealing means (not shown) are of course provided for that purpose. Once the injection is complete, and with the plunger fully depressed, the piston engages the lugs 56 on the hubs that shut the hub together with the needle can be drawn back into the barrel of the syringe. Due to the asymmetric nature of the lugs 56 and the resilience of the legs and connector part, the needle tip 28 is displaced through about 5° as it is pulled back so that it is no longer in line with the aperture at the neck of the barrel and this prevents re-extension of the needle and reuse of the syringe. With the needle fully withdrawn into the barrel the whole assembly can be discarded. Subject to local procedures, e.g. of a medical centre in which the device is used, it may be permissible for the unit to be consigned to general waste rather than a sharps bin requiring special handling and disposal.

In the case of fluid extraction from the body, e.g. of blood, the plunger may be depressed to a point short of where the lugs 56 engage with the connector part 12, and the plunger may then be retracted as fluid is drawn in. When the fluid is transferred into a vial (not shown) or other receptacle (not shown) the plunger will be fully depressed such that it engages with the lugs. Accordingly, when the plunger is pulled back again, the needle is withdrawn into the barrel of the syringe and the unit can be discarded.

In devices such as catheters or butterflies which are in turn connected to a drip or other equipment for the purpose of e.g. administering fluids into the body, the locking of the needle is secured by pulling the tail-end of the device until the needle disappears into the device.

Further advantages of preferred embodiments of the present invention will be apparent in that needles may be interchanged before use so that the clinician or other user can match a selection of needles with a selection of barrels. Thus, a standard barrel may be capable of taking a range of needle sizes and profiles, while larger or smaller barrels may be supplied for applications falling outside the most commonly used sizes. Accordingly, the system is very flexible. Sometimes, there is a requirement when preparing an injection for a first needle to draw the fluid from a vial and another to perform the injection using the same barrel. Of course, the preferred embodiments of the present invention are able to meet this requirement.

It is envisaged that blood collection (phlebotomy) may be used with embodiments of the invention, thus making "self-blunting" needles unnecessary.

Due to the removability of the needles in preferred embodiments of the invention, it is possible to keep barrels and needles apart before use. This gives flexibility and choice to e.g. the clinician who also has security and cost-saving implications since stores of syringes are readily targeted and robbed by drug users and medical personnel may also be targeted for theft. Accordingly, the ability to keep needles separately from barrels can reduce the risk of problems.

Another advantage is that preferred embodiments of the invention may allow a plunger and safety needle to be fitted to a prefilled container, subject to dimensions, with a secure seal between the barrel and needle mounting.

This is important since some prefilled syringes such as glass syringes for Meningitis immunisation do not always have in the prior art a needle which sits tightly in the neck of the barrel and fluid leaks out. A further particular advantage is that devices such as hypodermic needles in accordance with preferred embodiments of the present invention may be simple to use compared to other safety syringes and may be priced at a level affordable to health services and workers in most countries since the cost may be similar to that of standard, i.e. basic reusable products.

The connector part 14 may be adapted such that in other embodiments, once the connector part is engaged with the retainer part, the full length of the legs 30 is located inside the connector part such that there is no passage for fluid past the connector part along the needle and the needle cannot therefore be used again to suck fluid into the barrel.

Hubs 84 for needles of different sizes may be colour-coded to provide helpful information.

The syringe assembly 62 is preferably rubber-free, including the O ring 78. Instead of using a push-on hub 84 as shown in Figs. 4A to 4F for a syringe assembly 62 (it will be appreciated that the hub 84 snap-locks onto the front of the barrel in a conventional way), a half-turn/screw-lock may be implemented for the engagement of the hub 84 with the barrel 64, this generally being considered the American connection method, whereas the traditional conical snap connection system is used more in Europe.

The barrel of the syringe assembly 62 may be made from various materials including medical grade polypropylene. Alternatively, a clear polycarbonate may be used. Other materials may be used. Once assembled, the medical device/syringe assembly may be sterilised, for example, using ethylene oxide or gamma rays or an electron beam method. The plunger

may be made from various materials including polyurethane or other suitable materials and the plunger may be coloured, for example red or yellow or other suitable colours. The retainer part and connector part of the locking mechanism are preferably formed in plastics material and the needle is most preferably steel, being rolled, welded, cut and polished in a conventional way.

Fig. 10 shows a modification of the assembly shown in Fig. 4. The syringe barrel 100 in this embodiment has an eccentrically located forward neck portion 102, as shown in Fig. 10, which also shows finger tabs 104 of the assembly. As shown in Fig. 12, the needle 106 is retained by a retainer 12 the same as that shown in Figs. 8 to 10 and the plunger 108 has a connector part 104 located in an eccentric position corresponding to the position of the neck 102 and needle 106, the connector part 14 being as shown and described with reference to the embodiments of Figs. 1 to 4 and 7 to 9. The assembly in Figs. 10 and 12 includes an eccentrically domed hub 110. The plunger 108 has a stem 112 with an X-shaped section. One arm 114 of the stem 112 runs in a groove 116 defined by two grooved plates 118, only one of which is shown in Fig. 12, the plates preventing rotation of the plunger and stem. Fig. 11 shows an alternative embodiment similar to the embodiment of Fig. 10, but the barrel 100 of the syringe assembly has a non-circular section, namely an elliptical section. In this embodiment, the groove and plates 116,118 may be omitted. It will be appreciated that the side view of the Fig. 11 embodiment is shown in Fig. 12, as is the side view of the Fig. 10 embodiment. In both of these embodiments, the needle 106 is retained in place by lugs 46 on an internal recess of the syringe, and, once fully depressed, the connector part 14 on the plunger 108 engages with the retainer part 12, and the needle 106 is then retracted inside the syringe

assembly, on retraction of the plunger 108.

The use of a medical device such as a syringe assembly having an eccentric neck portion may be desirable in cases in which the cross-dimension or diameter of the assembly is relatively large. The eccentric location of the neck portion may enable a user of the assembly to place the assembly relatively close to or relatively parallel to a body surface of a patient, for example, for inserting a needle at a shallow angle into a patient.

In the syringe assemblies of Fig. 4 and Figs. 10 to 12, an important advantage is that the retainer 12 and needle 22 may be compatible with various syringe plunger devices or other devices and/or that the neck of the syringe may be connected to various types of device such as a needle with hub or a tube for pushing or sucking fluid along the tube. Thus, one type of locking mechanism/needle may be applicable to various devices, thus reducing costs. For example, the same locking mechanism, i.e. retainer part 12 and connector part 14 may be used in 1,5,10,20ml or other sizes of hypodermic syringe assembly. Instead of using the bubble or dome-shaped hub 84 shown in Figs. 4A to 4F and the eccentric bubble or dome-shaped hub shown in Fig. 12, a standard hub like the hub 84' may be employed.

Devices in accordance with the invention may have application in either human medical or veterinary fields and may even have application outside medical fields.

Various modifications may be made to the embodiments shown without departing from the scope of the invention as defined by the claims as interpreted under Patent Law.

CLAIMS

1. A locking mechanism for controlling engagement between parts movable relative to one another in medical sharp devices, the mechanism comprising: a retainer part for retaining a medical sharp, the retainer part having a fixed formation which is engageable with a second formation located on a body part of a medical sharp device and a connector part which is movable relative to the body part to a position in which the connector part and retainer part are in a mutually engaged configuration, wherein the connector part, during movement to the engaged configuration, is adapted to alter the relative engagement between the first and second formations to enable release of the retainer part from the body part.

2. A locking mechanism as claimed in claim 1 in which the first formation and second formation comprise a lug and a recess, each being formed on or in one of the retainer part and the body part.

3. A locking mechanism as claimed in claim 2 in which a pair of said lugs are provided on opposite sides of the retainer part and in which the recess comprises an internal annular recess in the body part.

4. A locking mechanism as claimed in any preceding claim in which the retainer part includes a flexible leg, the first formation being located on the leg, the connector part being adapted to flex the leg, on engagement with the retainer part, to move the first formation relative to the body part.

5. A locking mechanism as claimed in claim 4 when dependent upon

claim 3 in which the retainer part includes two said legs, the connector part being adapted to move the legs towards one another on engagement with the retainer part.

6. A locking mechanism as claimed in claim 5 in which the legs are mutually joined at respective ends thereof.

7. A locking mechanism as claimed in claim 6 in which the legs form a diamond shape.

8. A locking mechanism as claimed in any one of claims 4 to 7 in which each leg has an inner surface and an outer surface, the outer surface being longer than the inner surface.

9. A locking mechanism as claimed in claim 8 in which the inner surface is relatively flat and the outer surface is outwardly concave or relatively curved compared to the inner surface.

10. A locking mechanism as claimed in any preceding claim in which the connector part includes a bore into which at least part of the retainer part is insertable.

11. A locking mechanism as claimed in claim 10 in which the bore includes an annular ledge at an entrance thereto, and in which the retainer part includes at least one connector protrusion for engagement behind the annular ledge.

12. A locking mechanism as claimed in claim 11 in which two said connector protrusions are provided, the connector protrusions being adapted to engage the annular ledge asymmetrically.

13. A locking mechanism as claimed in claim 12 in which each connector protrusion has a chamfered surface for riding over the annular ledge and an opposing step surface for engagement behind the ledge.

14. A locking mechanism as claimed in any preceding claim in which the retainer part is adapted to retain a hypodermic needle, the retainer part including an elongate bore passing therethrough, the bore being engageable with a cylindrical outer surface of a needle.

15. A locking mechanism as claimed in claim 14 in which the elongate bore includes internal ribs for sealingly gripping a needle.

16. A locking mechanism for a medical device comprising a retainer part for retaining medical sharp devices, the retainer part including at least one connector portion thereof adapted for engagement against a body part of a medical sharp device, and a connector part, the connector part being adapted for movement to engage the connector portion for connection therewith, movement of the connector part once connected to the connector portion causing movement of the retainer part.

17. A locking mechanism as claimed in claim 16 in which the connector portion comprises a flexible leg.

18. A locking mechanism as claimed in claim 17 in which two said flexible legs are provided extending generally parallel to one another, engagement of the connector part with the legs causing the legs to move towards one another.

19. A locking mechanism as claimed in claim 18 in which the legs are joined together in a diamond shape.

20. A locking mechanism as claimed in any one of claims 17 to 19 in which each said leg includes a lug adapted for engagement with a recess formed in the body part, the movement of the connector part to engage the leg causing a reduction in the force of engagement between the lug and recess.

21. A locking mechanism as claimed in any one of claims 17 to 20 in which the connector part includes a generally cylindrically bore, the bore being adapted to receive each said leg on engagement of the connector part therewith.

22. A locking mechanism as claimed in claim 21 in which the bore includes an annular ledge at an entrance thereto and each said leg includes a connector projection adapted to ride over and lock past the ledge on insertion to the bore.

23. A hypodermic needle assembly comprising a generally cylindrical needle and a retainer for the needle, the retainer having an elongate bore formed therethrough, the needle being a push-fit in the bore for sealing

engagement therein.

24. A hypodermic needle assembly as claimed in claim 23 in which the bore includes a series of ribs for sealingly engaging an outer surface of the needle.

25. An assembly as claimed in claim 24 in which the ribs are circumferentially extending ribs.

26. A hypodermic needle assembly comprising a fluid container for sealably maintaining fluid therein, the container having a main body connected at one end thereof via a shoulder to a generally cylindrical neck portion having an open front end, and a needle retainer assembly comprising a needle retainer and a needle, the needle retainer being removably insertable through the open front end of the neck portion into the neck portion of the fluid container.

27. An assembly as claimed in claim 26 in which the fluid container comprises a generally cylindrical barrel.

28. An assembly as claimed in claim 26 or claim 27 in which the needle retainer has a cylindrical body and has a bore formed therealong, the bore having an entrance thereto, the needle retainer being insertable into the neck portion to a position in which the entrance to the bore is located spaced at least partly along the neck portion from the open front end thereof to the shoulder.

29. An assembly as claimed in claim 28 in which the needle portion is insertable into the neck portion into a position in which the entrance to the bore is axially located about 50% to 100% (e.g. about 75% or more) of the way along the neck portion from the open end to the shoulder thereof.

30. An assembly as claimed in any one of claims 28 to 29 in which the needle retainer and neck portion are circularly cylindrical, and in which an outer diameter of the needle retainer is substantially equal to an inner diameter of the neck portion.

31. An assembly as claimed in any one of claims 26 to 30 in which the fluid container is formed with an annular internal recess at the axial point at which the neck portion meets the shoulder portion thereof, and in which the needle retainer includes at least one projection adapted to engage with the recess for retaining the needle retainer in position in the fluid container.

32. An assembly as claimed in claim 31 in which the projection is releasable from the recess for enabling movement of the needle assembly along the fluid containers.

33. An assembly as claimed in any one of claims 26 to 32 in which a seal is provided on the needle retainer for sealing with the internal surface of the neck portion.

34. An assembly as claimed in claim 33 in which the needle retainer has a cylindrical body having a front end from which the needle projects and a rear end, the seal being located adjacent the rear end.

35. An assembly as claimed in any one of claims 26 to 34 in which the needle has a sharp front end, and a rear end, the rear end being adjacent a rear end of a cylindrical body of the needle retainer.

36. An assembly as claimed in any one of claims 26 to 35 which includes means for forcing fluid out of the container and along the needle.

37. A medical device including a needle assembly as claimed in any one of claims 16 to 36.

38. A medical device including a locking mechanism as claimed in any one of claims 1 to 25.

39. A medical device as claimed in claim 38 which comprises a hypodermic needle device.

40. A medical device as claimed in claim 39 which comprises a butterfly.

41. A medical device as claimed in claim 39 which comprises a catheter.

42. A medical device as claimed in claim 39 which comprises a hypodermic syringe and in which the retainer part is adapted to retain a hypodermic needle of the device and the connector part is mounted on a plunger of the syringe.

43. A medical device as claimed in claim 42 in which the syringe has an

eccentrically located neck portion and the connector part is located in a corresponding eccentric located on the plunger.

44. A medical device as claimed in claim 43 in which means are provided for preventing rotation of the plunger in a barrel portion of the syringe.

45. A medical device as claimed in claim 42 or 43 or 44 in which the syringe includes a barrel, a conical shoulder portion at a forward end of a main cylindrical part of the barrel and a neck portion in front of the shoulder portion, the said second formation of the locking mechanism being formed internally in the neck portion.

46. A medical device as claimed in claim 45 in which the neck portion of the barrel includes a front end and a rear end, the rear end being adjacent a front end of the shoulder portion, the second formation comprising an annular internal recess formed at the rear end of the neck portion.

47. A medical device as claimed in any one of claims 38 to 45 in which the retainer part is removably mounted on the body part of the device.

48. A medical device as claimed in claim 47 when dependent upon claim 25 which includes a hub part for releasably sealably retaining the retainer part on the barrel of the syringe.

49. A medical device as claimed in claim 48 in which the hub includes a stop surface for preventing forward movement of the retainer part relative to the barrel.

50. A locking mechanism substantially as described herein with reference to the accompanying drawings.

51. A hypodermic needle assembly substantially as described herein with reference to the accompanying drawings.

52. A medical device substantially as described herein with reference to the accompanying drawings.

53. A syringe device having a barrel portion, a plunger located in the barrel, the barrel portion having an eccentrically located neck at one end thereof, and means provided for preventing rotation of the plunger in the barrel.

54. A device as claimed in claim 53 in which the means for preventing rotation comprise the barrel having a non-circular cross section and the plunger has a corresponding cross section.

55. A device as claimed in claim 54 in which the barrel has a elliptical cross section.

56. A device as claimed in any one of claims 53 to 55 in which the plunger has a stem with an X-shaped section and the barrel is formed with a groove allowing axial movement but preventing rotation of the plunger stem.

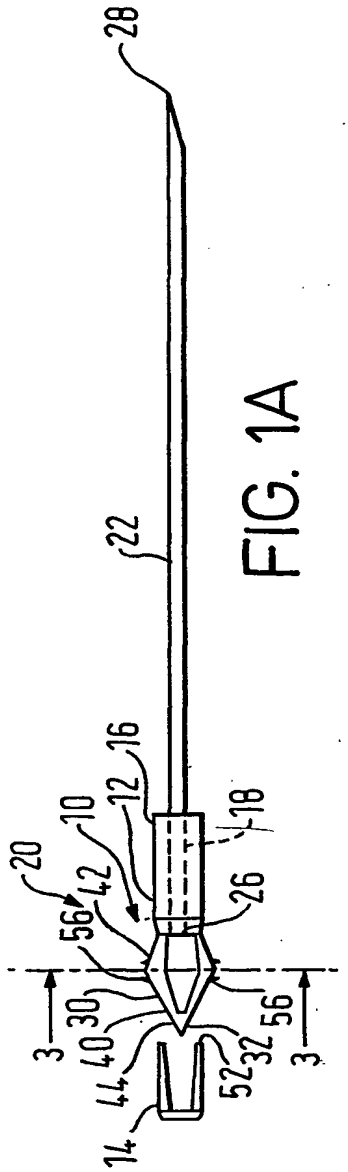


FIG. 1A

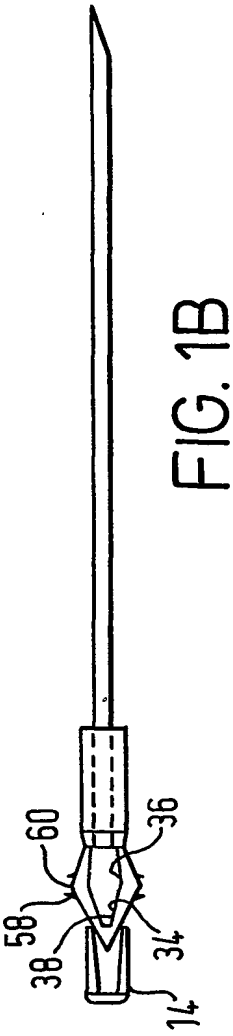


FIG. 1B

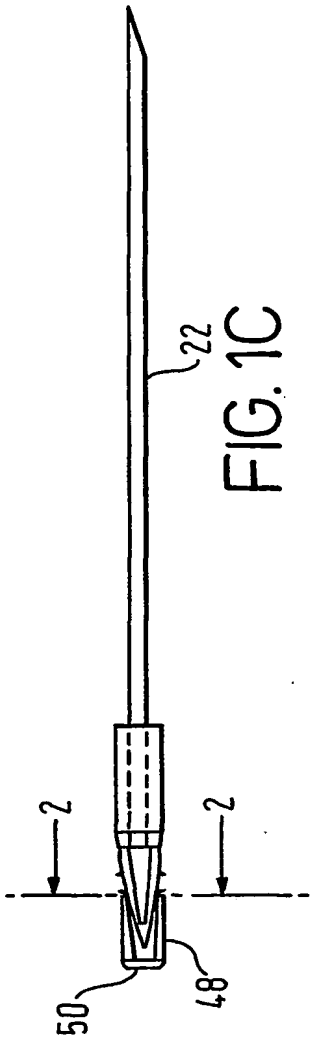


FIG. 1C

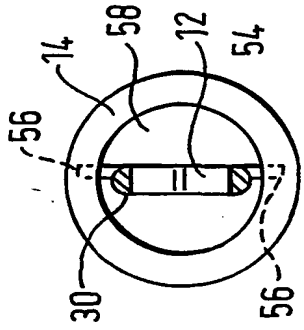


FIG. 2

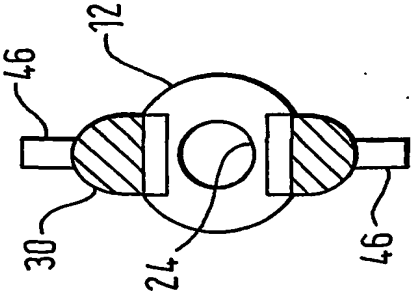


FIG. 3

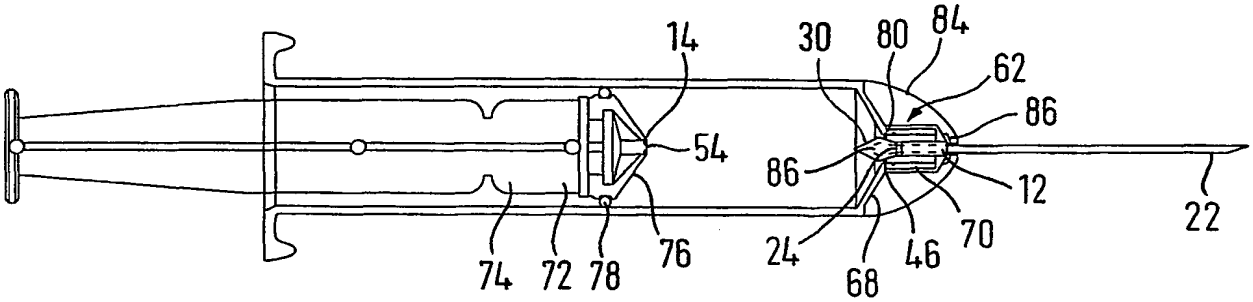


FIG. 4A

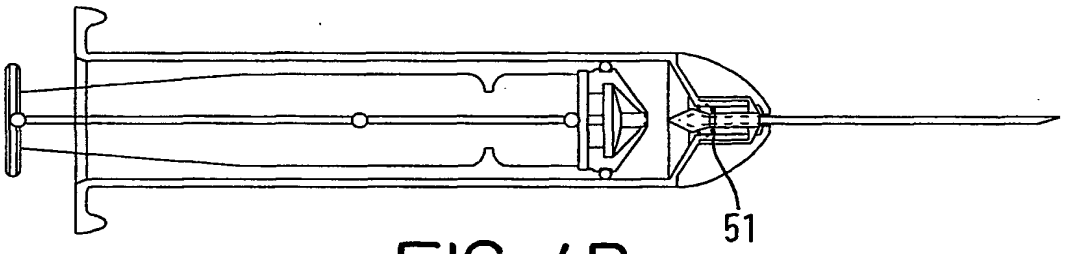


FIG. 4B

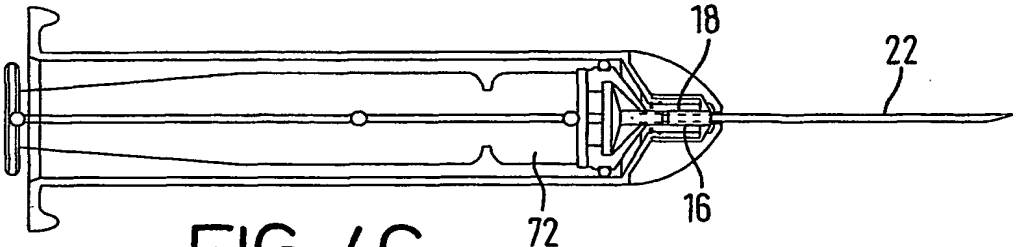


FIG. 4C

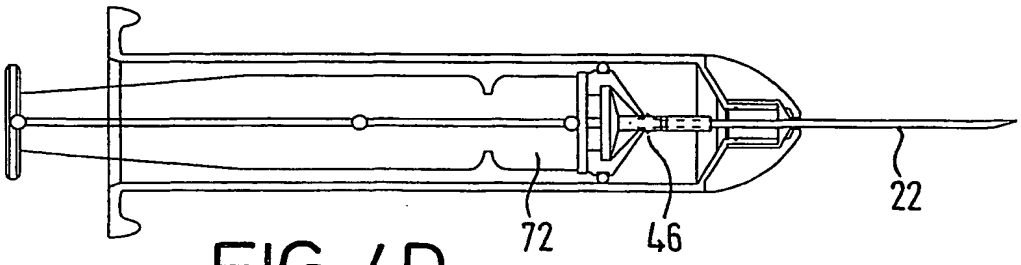


FIG. 4D

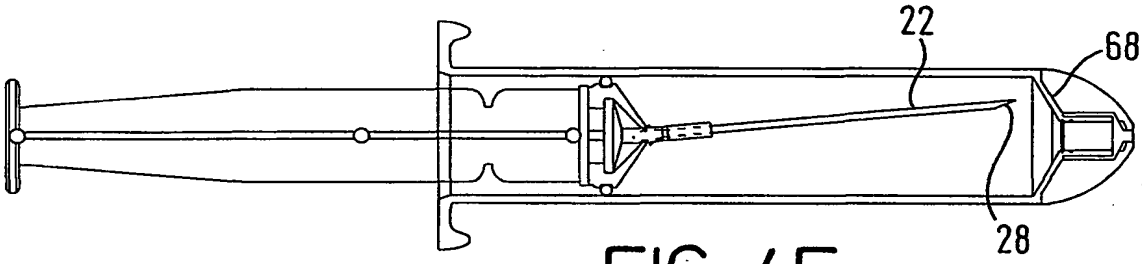


FIG. 4E

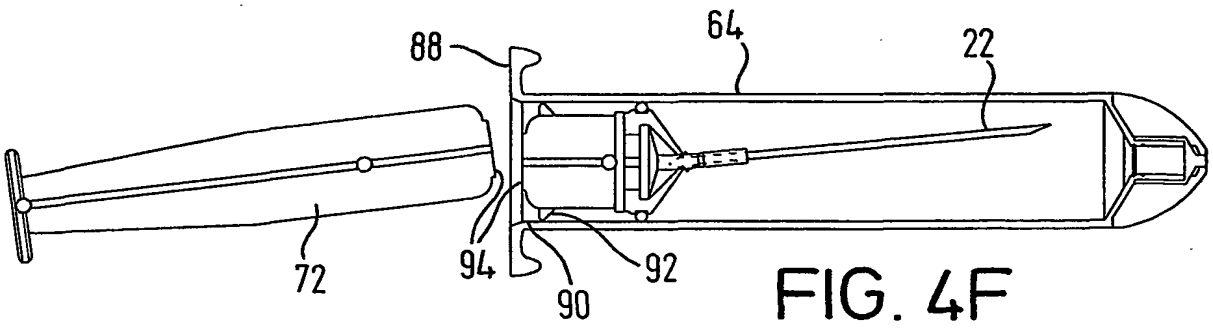


FIG. 4F

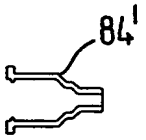


FIG. 5

FIG. 6A

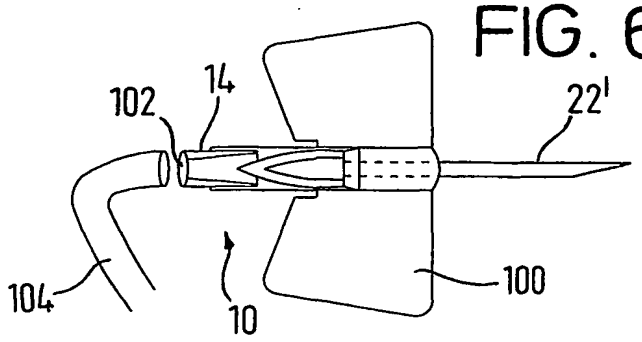


FIG. 6B

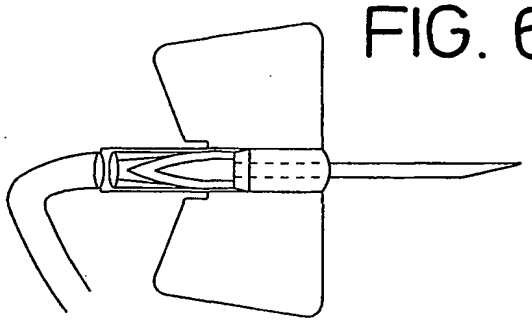


FIG. 6C

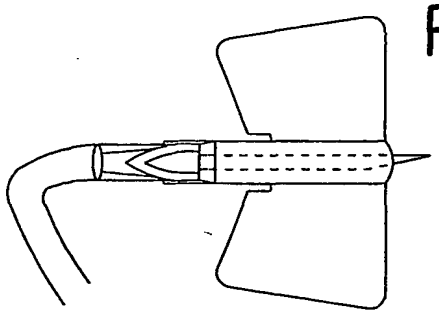
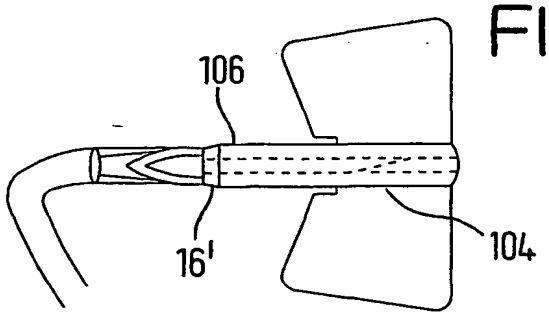


FIG. 6D



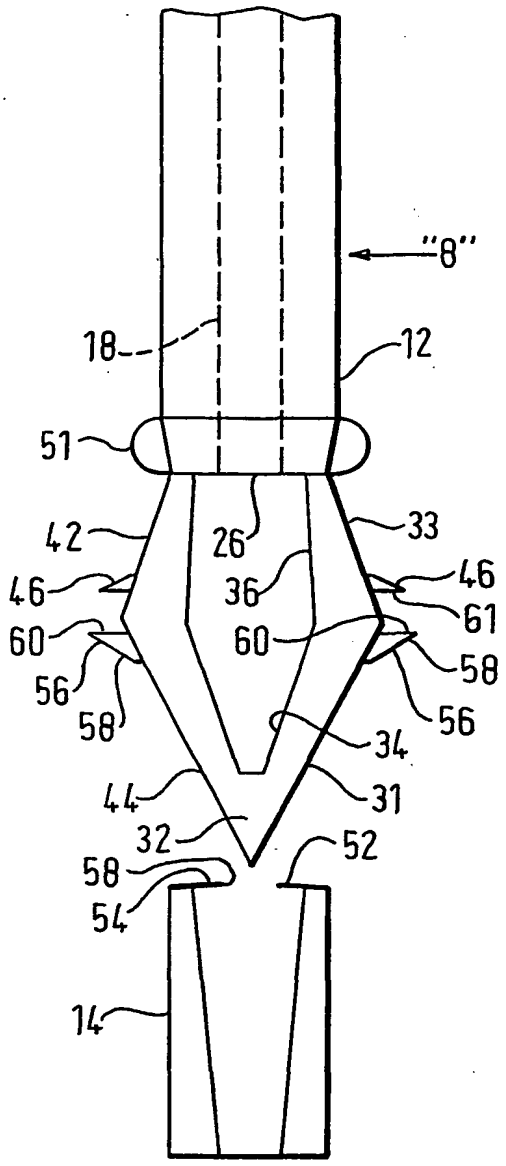

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FIG. 7

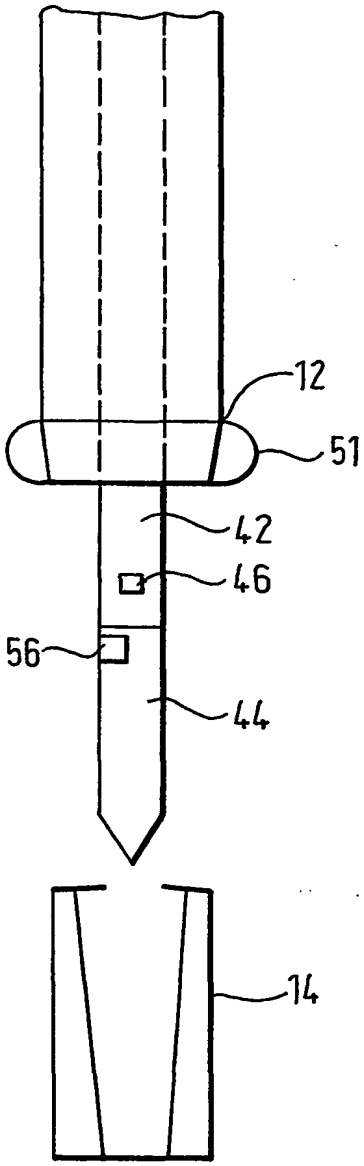
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FIG. 8

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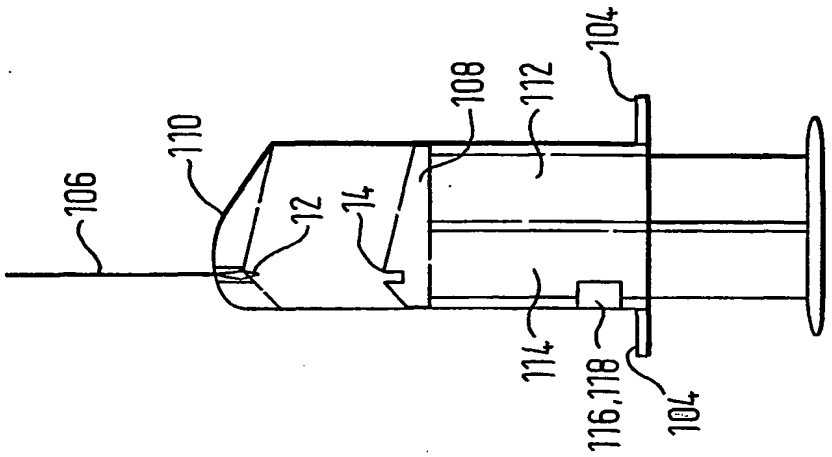

FIG. 12

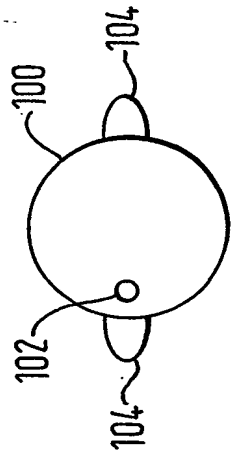

FIG. 10

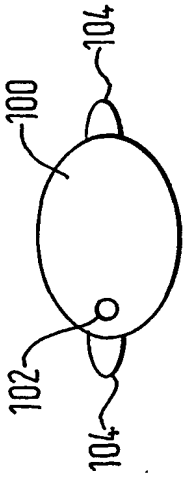

FIG. 11

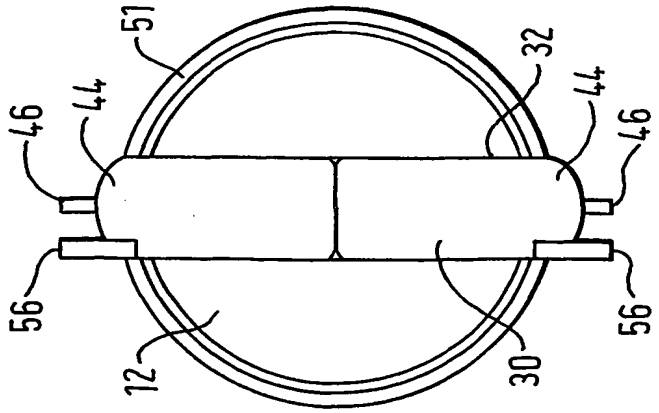

FIG. 9

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(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MASTORAKIS, Emmanuel** [GR/MC]; 10, rue St. Pierre, CP 447, CH-1701 Fribourg (CH).

(74) Agents: **MILLER, James, Lionel, Woolverton** et al.; Kilburn & Strode, 20 Red Lion Street, London WC1R 4PJ (GB).

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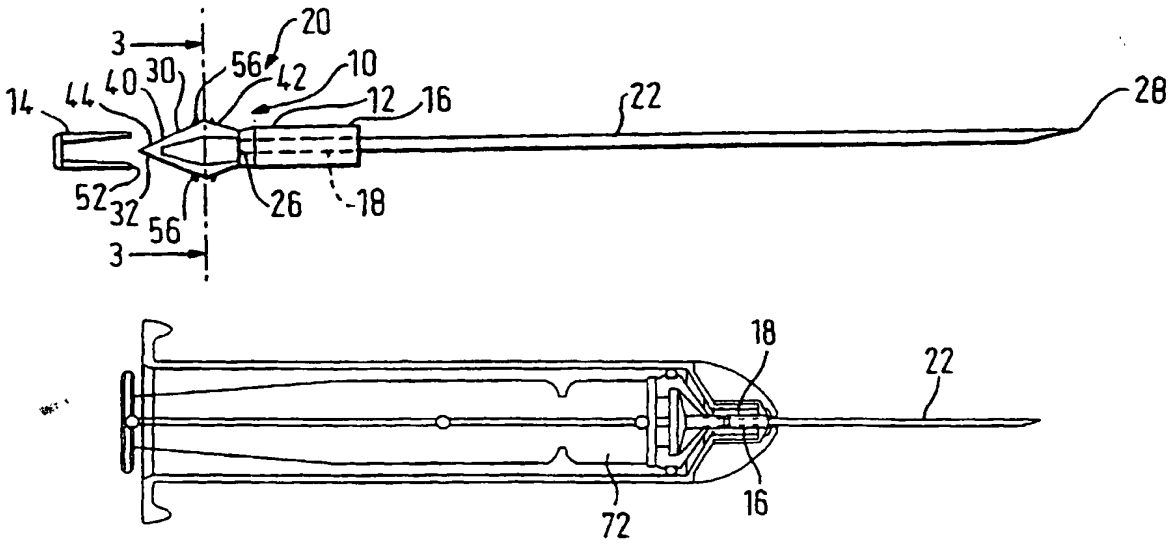
Published:
— *with international search report*
— *upon request of the applicant, before the expiration of the time limit referred to in Article 21(2)(a)*

[Continued on next page]

(54) Title: MEDICAL DEVICE AND LOCKING MECHANISM THEREFOR



(57) Abstract: A locking mechanism (10) for a medical sharp device such as a syringe assembly (62) includes a retainer part (12) for retaining a hypodermic needle (22), and a connector part (14). The retainer part includes lugs (46) for engagement with a recess (82) formed in a neck (70) of the syringe assembly. When a plunger (72) of the syringe assembly is pushed fully forwards, the lugs (56) of the retainer part (12) engage behind a ledge (54) of the connector part (14) and the lugs (46) disengage from the recess (82). The plunger (72) may then be retracted, pulling the needle (22) into the barrel (64) of the assembly. The neck portion may be eccentrically mounted on the barrel and means (116, 118) may be provided for preventing rotation of the plunger (72) in the barrel (64).

WO 02/26295 A3

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13 June 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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Internal Application No
PCT/EP 01/00817

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 718 358 A (MERCHIN CHARLES;ELFANDI PATRICE) 13 October 1995 (1995-10-13) page 7, line 24 -page 8, line 7 page 8, line 33 - line 35 page 9, line 34 -page 10, line 20 figures	1-5, 8-11, 16-18, 20-22, 37-39, 42,47
A	---	45,46
X	US 4 904 242 A (KULLI JOHN C) 27 February 1990 (1990-02-27) column 11, line 27 - line 48 figures	1,2,10, 11,16
A	---	3,12,21, 22
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 August 2001	26. 03. 2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	SEDY R.

Form PCT/ISA/210 (second sheet) (July 1992)

INT NATIONAL SEARCH REPORT

International Application No
PCT/EP 01/00817

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 047 016 A (TORBET PHILIP ET AL) 10 September 1991 (1991-09-10) column 7, line 34 -column 8, line 9 figures 7-9	1,10,14, 16-18, 38,39, 42,47
A		2-5,8, 11-13, 45,46

A	US 5 976 108 A (LIU WEN-NENG) 2 November 1999 (1999-11-02) figures 13,14	33,34

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 01/00817

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 50, 51, 52
because they relate to subject matter not required to be searched by this Authority, namely:

PCT Rule 6.2(a)

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-15, 16-22, 37, 38-42, 45-47

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-15, 16-22, 37 (when dependent of claims 16-22), 38-42 and 45-47 (when dependent of claims 1-22)

locking mechanism for controling engagement between parts movable relative to one another in medical sharp devices having
claim 1: retainer part with first formation, second formation located on a body part of the sharp device and connector part to alter relative engagement between the first and second formations;
claim 16: retainer part including connector portion, connector part;

2. Claims: 23-25, 38-42 and 45-47 (when dependent of claims 23-25), 48,49

hypodermic needle assembly having a needle, retainer with elongate bore, push-fit between needle and bore;

3. Claims: 26-42, 37 (when dependent of claims 23-36)

hypodermic needle assembly having a fluid container, main body with shoulder, cylindrical neck portion and open front end, needle retainer being removabely insertable through the open front end of the neck portion and having needle retainer and needle;

4. Claims: 43, 44, 53-56

claim 43: medical device having a syringe with an eccentrically located neck portion and an eccentrically located connector part located on a plunger;
claim 53: syringe device having a barrel portion, plunger, barrel portion having an eccentrically located neck, means for preventing rotation of plunger in a barrel.

INT. .NATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 01/00817

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2718358 A	13-10-1995	FR 2718358 A1	13-10-1995
		WO 9527524 A1	19-10-1995
US 4904242 A	27-02-1990	US 4747831 A	31-05-1988
		AT 134522 T	15-03-1996
		AU 665335 B2	04-01-1996
		AU 1536688 A	03-11-1988
		DE 3855022 D1	04-04-1996
		DE 3855022 T2	21-11-1996
		EP 0290176 A1	09-11-1988
		EP 0719564 A1	03-07-1996
		ES 2086296 T3	01-07-1996
		NZ 224396 A	26-03-1996
		US 4927414 A	22-05-1990
		US 4900307 A	13-02-1990
		ZA 8802700 A	28-12-1988
US 5047016 A	10-09-1991	US 5108379 A	28-04-1992
		AU 2672888 A	06-07-1989
		EP 0321903 A2	28-06-1989
		JP 2021876 A	24-01-1990
		US 4898589 A	06-02-1990
US 5976108 A	02-11-1999	NONE	

Atty. Docket No. KIL01 P-424
Express Mail No EL545347964US

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
KILBURN & STRODE
Attn. Miller, J.L.W.
20 Red Lion Street
London WC1R 4PJ
UNITED KINGDOM

K+S Received
Date: 03 SEP 2001
Entered:
Checked: P1016

INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

Applicant's or agent's file reference F/E JLWM/P31175WO	Date of mailing *(day/month/year)* 30/08/2001
	PAYMENT DUE within 30 ~~months~~/days from the above date of mailing
International application No. PCT/EP 01/00817	International filing date *(day/month/year)* 25/01/2001
Applicant NICODEL S.A.	

1. This International Searching Authority

(i) considers that there are 04 *(number of)* inventions claimed in the international application covered by the claims indicated ~~below~~/on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated ~~below~~/on the extra sheet:

(ii) [X] has carried out a partial international search (see Annex) [ ] will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:
1-15,16-22,37,38-42,45-47

(iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

2. The applicant is hereby **invited,** within the time limit indicated above, to pay the amount indicated below:

EUR 945,00 (Fee per additional invention) x 03 (number of additional inventions) = EUR 2.835,00 (total amount of additional fees)

Or, _____ x _____ = _____

The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fee may be made under protest,** i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. [X] Claim(s) Nos. 50,51,52 have been found to be unsearchabl und r Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Nathalie Geisler

AANGETEKEND
EINSCHREIBEN
RECOMMANDE
REGISTERED

Form PCT/ISA/206 (July 1992)

INVITATION TO PAY ADDITIONAL FEES

International application No.
PCT/EP 01/00817

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-15, 16-22, 37 (when dependent of claims 16-22), 38-42 and 45-47 (when dependent of claims 1-22)

   locking mechanism for controling engagement between parts movable relative to one another in medical sharp devices having
   claim 1: retainer part with first formation, second formation located on a body part of the sharp device and connector part to alter relative engagement between the first and second formations;
   claim 16: retainer part including connector portion, connector part;

2. Claims: 23-25, 38-42 and 45-47 (when dependent of claims 23-25), 48,49

   hypodermic needle assembly having a needle, retainer with elongate bore, push-fit between needle and bore;

3. Claims: 26-42, 37 (when dependent of claims 23-36)

   hypodermic needle assembly having a fluid container, main body with shoulder, cylindrical neck portion and open front end, needle retainer being removabely insertable through the open front end of the neck portion and having needle retainer and needle;

4. Claims: 43, 44, 53-56

   claim 43: medical device having a syringe with an eccentrically located neck portion and an eccentrically located connector part located on a plunger;
   claim 53: syringe device having a barrel portion, plunger, barrel portion having an eccentrically located neck, means for preventing rotation of plunger in a barrel.

The FR 2 718 358 document (D1) cited in the search report discloses a locking mechanism having retainer part with a fixed formation which is engageable with a second formation located on a body part of a medical sharp device and a connector part.
Additionally, D1 also discloses a hypodermic needle assembly having a fluid container having a main body, a shoulder and a cylindrical neck portion having open front an end, a needle retainer assembly with a needle retainer and a needle.

Over this prior art the potential special technical features (in the meaning of Rule 13.2 of the PCT) of the above defined groups are:

First group:

claim 6: legs are mutually joined at their ends, solving the problem of being squashed by the connector part;
claim 19: legs are joined together in a diamond shape, solving the problem of being squashed by the connector part;

Second group:

claim 23: push-fit engagement of needle in the bore of a retainer, solving the problem of costly manufacturing steps.

claim 48: hub part for releasably sealably retaining retainer part on the barrel, solving the problem of providing means for using retainers and needles of different configurations

Third group:

claim 28: needle retainer bore is located spaced along the neck portion, solving the problem of waisting injection fluid;

Fourth group:

claim 43: syringe with eccentrically located neck portion, solving the problem of difficult handling of medical devices having large diameter;

claim 53: means preventing rotation of plunger, solving the problem of coaxial misalignment between neck portion of syringe barrel and connector part of plunger.

The above analysis shows that the potential special technical features of the different groups of inventions are not the same.

A comparison of the problems related to the different groups of inventions, all seen in the light of the description and drawings of the application, shows that they are all different and have no corresponding technical effect. Consequently, the special technical features are not only different but are also not corresponding.

Therefore, a technical relationship among the different inventions involving one or more of the same or corresponding special technical features, can not be found and consequently the requirement of unity of invention is not fulfilled.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 3.

Claims Nos.: 50, 51, 52

PCT Rule 6.2(a)

Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS OF THE PARTIAL INTERNATIONAL SEARCH

International Application No
PCT/EP 01/00817

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relat to the invention first mentioned in claims Nos.:
1-22,37-42,45-47

2. This communication is not the international search report which will be established according to Article 18 and Rule 43.

3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.

4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 718 358 A (MERCHIN CHARLES;ELFANDI PATRICE) 13 October 1995 (1995-10-13) page 7, line 24 -page 8, line 7 page 8, line 33 - line 35 page 9, line 34 -page 10, line 20 figures	1-5, 8-11, 16-18, 20-22, 37-39, 42,47
A	---	45,46
X	US 4 904 242 A (KULLI JOHN C) 27 February 1990 (1990-02-27) column 11, line 27 - line 48 figures	1,2,10, 11,16
A	---	3,12,21, 22
X	US 5 047 016 A (TORBET PHILIP ET AL) 10 September 1991 (1991-09-10) column 7, line 34 -column 8, line 9 figures 7-9	1,10,14, 16-18, 38,39, 42,47
A	---	2-5,8, 11-13, 45,46
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

2

Form PCT/ISA/206 (Annex, first sheet) (July 1992)

Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No
PCT/EP 01/00817

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 976 108 A (LIU WEN-NENG) 2 November 1999 (1999-11-02) figures 13,14	33,34

2

Patent Family Ann x

Information on patent family members

International Application No
/EP 01/00817

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2718358 A	13-10-1995	WO 9527524 A	19-10-1995
US 4904242 A	27-02-1990	US 4747831 A	31-05-1988
		AT 134522 T	15-03-1996
		AU 665335 B	04-01-1996
		AU 1536688 A	03-11-1988
		DE 3855022 D	04-04-1996
		DE 3855022 T	21-11-1996
		EP 0290176 A	09-11-1988
		EP 0719564 A	03-07-1996
		ES 2086296 T	01-07-1996
		NZ 224396 A	26-03-1996
		US 4927414 A	22-05-1990
		US 4900307 A	13-02-1990
		ZA 8802700 A	28-12-1988
US 5047016 A	10-09-1991	US 5108379 A	28-04-1992
		AU 2672888 A	06-07-1989
		EP 0321903 A	28-06-1989
		JP 2021876 A	24-01-1990
		US 4898589 A	06-02-1990
US 5976108 A	02-11-1999	NONE	

Kilburn & Strode

European Patent Attorneys
Chartered Patent Attorneys
Trade Mark Attorneys

20 Red Lion Street
London WC1R 4PJ
Tel: +44 (0)20-7539 4200
Fax: +44 (0)20-7539 4299
Email: ks@kstrode.co.uk

European Patent Office
Patentlaan 2
Post Box 5818
2280 HV Rijswijk (ZH)
Netherlands

For the attention of PCT Receiving Office

Our Ref: **P31175WO/JLWM**
Your Ref:

31 July 2001

BY DHL COURIER

Dear Sirs

International (PCT) Patent Application No. PCT/EP01/00817
In the name of Nicodel S.A

We now file a certified copy of the priority application, Greek Application No. 20000100459 in connection with this case. Also filed herewith is a copy of a further certification from the Greek Patent Office, confirming that the required supplementary documents for the completion of the file of the patent application were filed.

Yours faithfully

J L W Miller
Authorised Representative
KILBURN & STRODE

Atty. Docket No. KIL01 P-424
Express Mail No EL545347964US

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF RECEIPT OF SEARCH COPY

(PCT Rule 25.1)

K+S Received
Date: 29 MAR 2001
Entered:

To:
KILBURN & STRODE
Attn. Miller, J.L.W.
20 Red Lion Street
London WC1R 4PJ
UNITED KINGDOM

Date of mailing *(day/month/year)*: 27/03/2001

Applicant's or agent's file reference: JLWM/P31175WO

IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 01/00817	25/01/2001	22/12/2000

Applicant: NICODEL S.A.

1. **Where the International Searching Authority and the Receiving Office are not the same office:**

The applicant is hereby notified that the search copy of the international application was received by this International Searching Authority on the date indicated below.

Where the International Searching Authority and the Receiving Office are the same office:

The applicant is hereby notified that the search copy of the international application was received on the date indicated below.

09/03/2001 *(date of receipt).*

2. ☐ The search copy was accompanied by a nucleotide and/or amino acid sequence listing in computer readable form.

3. **Time limit for establishment of International Search Report**

The applicant is informed that the time limit for establishing the International Search Report is 3 months from the date of receipt indicated above or 9 months from the priority date, whichever time limit expires later

4. A copy of this notification has been sent to the International Bureau and, where the first sentence of paragraph 1 applies, to the Receiving Office.

Name and mailing address of the International Searching Authority:
European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 po nl,
Fax: (+31-70) 340-3016

Authorized officer: ISA/EP

Form PCT/ISA/202 (July 1998)

PATENT COOPERATION TREATY

NOTIFICATION OF RECEIPT OF RECORD COPY

(PCT Rule 24.2(a))

From the INTERNATIONAL BUREAU

To:

MILLER, James, Lionel, Woolverton
Kilburn & Strode
20 Red Lion Street
London WC1R 4PJ
ROYAUME-UNI

Date of mailing (day/month/year)	IMPORTANT NOTIFICATION
27 February 2001 (27.02.01)	
Applicant's or agent's file reference	**International application No.**
JLWM/P31175WO	PCT/EP01/00817

The applicant is hereby notified that the International Bureau has received the record copy of the international application as detailed below.

Name(s) of the applicant(s) and State(s) for which they are applicants:

NICODEL S.A. (for all designated States except US)
MASTORAKIS, Emmanuel (for US)

International filing date	:	25 January 2001 (25.01.01)
Priority date(s) claimed	:	22 December 2000 (22.12.00)
Date of receipt of the record copy by the International Bureau	:	13 February 2001 (13.02.01)
List of designated Offices	:	

AP :GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZW
EA :AM,AZ,BY,KG,KZ,MD,RU,TJ,TM
EP :AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE,TR
OA :BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG
National :AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CR,CU,CZ,DE,DK,DM,DZ,EE, ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KP,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA, MD,MG,MK,MN,MW,MX,MZ,NO,NZ,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,US, UZ,VN,YU,ZA,ZW

ATTENTION

The applicant should carefully check the data appearing in this Notification. In case of any discrepancy between these data and the indications in the international application, the applicant should immediately inform the International Bureau.

In addition, the applicant's attention is drawn to the information contained in the Annex, relating to:

- [X] time limits for entry into the national phase
- [ ] confirmation of precautionary designations
- [X] requirements regarding priority documents

A copy of this Notification is being sent to the receiving Office and to the International Searching Authority.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer:
David Lopez-Ramirez

Telephone No. (41-22) 338.83.38

Kilburn & Strode

European Patent Attorneys
Chartered Patent Attorneys
Trade Mark Attorneys

20 Red Lion Street
London WC1R 4PJ
Tel: +44 (0)20-7539 4200
Fax: +44 (0)20-7539 4299
Email: ks@kstrode.co.uk

European Patent Office
Patentlaan 2
Post Box 5818
2280 HV Rijswijk (ZH)
Netherlands

For the attention of PCT Receiving Office, Mrs H Fransz

Our Ref: **P31175WO/JLWM**
Your Ref:

5 March 2001

Dear Sirs

International (PCT) Patent Application No. PCT/EP01/00817
In the name of Nicodel S.A

We reply to the Official Communication of 9 February 2001.

We enclose herewith a PCT General Power of Attorney which has been executed by both applicants, Nicodel S.A., and Emmanuel Mastorakis.

Yours faithfully

KILBURN & STRODE

Enclosure

Atty. Docket No: KIL01 P-424
Express Mail No EL545347964US

PATENT COOPERATION TREATY

From the RECEIVING OFFICE

PCT

To:
Miller, J.L.W.
KILBURN & STRODE
20 Red Lion Street
London WC1R 4PJ
GRANDE BRETAGNE

K + S Received
Date: 12 FEB 2001
Entered:
Checked:
F/E

INVITATION TO CORRECT DEFECTS IN THE INTERNATIONAL APPLICATION

(PCT Articles 3(4)(i) and 14(1) and Rule 26)

Applicant's or agent's file reference JLWM/P31175WO	Date of mailing *(day/month/year)* 09 FEB 2001 **REPLY DUE** within **two months** from the above date of mailing
International application No. PCT/EP 01/ 00817	International filing date *(day/month/year)* 25/01/2001
Applicant NICODEL S.A.	

1. [X] The applicant is hereby **invited,** within the time limit indicated above, to correct, **in the international application as filed,** the defects specified on the attached

   - [X] Annex A
   - [ ] Annex B1 *(text matter of the international application as filed)*
   - [ ] Annex C1 *(drawings of the international application as filed)*

Additional observations (if necessary):

HOW TO CORRECT THE DEFECTS ?

Correction must be submitted by filing a replacement sheet embodying the correction and a letter accompanying the replacement sheet, which shall draw attention to the difference between the replaced sheet and the replacement sheet. A correction may be stated in a letter only if it is of such a nature that it can be transferred from the letter to the record copy without adversely affecting the clarity and direct reproducibility of the sheet onto which the correction is to be transferred (Rule 26.4).

ATTENTION

Failure to correct the defects will result in the international application being considered withdrawn by this receiving Office (see Rule 26.5 for further details).

A copy of this invitation and any attachments has been sent to the International Bureau

- [ ] and the International Searching Authority.

Name and mailing address of the receiving Office European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Mrs. H. Fransz

Form PCT/RO/106 (July 1998)

ANNEX A TO FORM PCT/RO/106

International application No.
PCT/EP 01/00817

The receiving Office has found the following defects in the international application as filed:

1. As to **signature*** of the international application (Rules 4.15 and 90.4), the request :

   a. ☐ is not signed.

   b. ☐ is not signed by all the applicants.

   c. ☐ is not accompanied by the statement referred to in the check list in Box No. VIII of the request explaining the lack of the signature of an applicant for the designation of the United States of America.

   d. ☒ is signed by what appears to be an agent/common representative but

      ☒ the international application is not accompanied by a power of attorney appointing him.

      ☐ the power of attorney accompanying the international application was not signed by all the applicants.

   e. ☐ other *(specify)* :

* All applicants must sign, including inventors if they are also applicants (e.g. where the United States of America is designated).

2. As to indications concerning the **applicant**, the request (Rules 4.4 and 4.5) :

   a. ☐ does not properly indicate the applicant's name *(specify)*:

   b. ☐ does not indicate the applicant's address.

   c. ☐ does not properly indicate the applicant's address *(specify)* :

   d. ☐ does not indicate the applicant's nationality.

   e. ☐ does not indicate the applicant's residence.

   f. ☐ other *(specify)* :

3. As to the **language** of certain elements of the international application, other than the description and claims (Rules 12.1(c) and 26.3*ter*(a) and (c)):

   a. ☐ the **request** is not in a language which is both a language accepted by this receiving Office and a language of publication, which are: ENGLISH, FRENCH or GERMAN.

   b. ☐ the **text matter of the drawings** is not in the language in which the international application is to be published, which is: ENGLISH.

   c. ☐ the **abstract** is not in the language in which the international application is to be published, which is: ENGLISH.

4. The **title** of the invention :

   a. ☐ is not indicated in Box No.I of the request (Rule 4.1(a)).

   b. ☐ is not indicated at the top of the first sheet of the description (Rule 5.1(a)).

   c. ☐ as appearing in Box No.I of the request is not identical with the title heading the description (Rule 5.1(a)).

5 As to the **abstract** (Rule 8) :

   ☐ the international application does not contain an abstract.

Express Mail No EL545347964US Atty. Docket No. KIL01 P-424

EUROPAISCHES PATENTAMT
Generaldirektion 1

EUROPEAN PATENT OFFICE
Directorate General 1

OFFICE EUROPEEN DES BREVETS
Direction générale 1

Patentlaan 2
2280 HV Rijswijk ZH
Nederland
Tel 070-3402040
Telex 31651
Fax 070-3403016

KILBURN & STRODE
20 Red Lion Street
London WC1R 4PJ
GRANDE BRETAGNE

01 FEB 2001

Client
F/E

Applicant:

NICODEL S.A.

Nr. der Anmeldung - Application N° - Demande de brevet n°	PCT/EP 01/ 00817
Tag des Eingangs - Date of Receipt - Date de réception	25/01/2001
Aktenzeichen des Anmelders/Anwalts - Applicant's/Agent's file reference - Coté du dossier du déposant ou du mandataire	JLWM/P31175WO

Datum / Date 30. 01. 01

Betreff: Empfangsbestätigung
Re: Receipt for documents
Objet: Récépissé de documents

Das Europäische Patentamt
The European Patent Office
L'Office européen des brevets

bestätigt hiermit den Empfang folgender Dokumente:
hereby acknowledges the receipt of the following:
accuse réception des documents indiqués ci-dessous:

A. Anmeldeunterlagen / items making up the application / pièces de la demande	Anzahl / N° of copies / Nombre d'exemplaires	B. Beigefügte Dokumente / accompanying documents / documents joints
☒ Antrag / Request / Requête	1	☐ Vertretervollmacht / Authorisation of representative(s) / Pouvoir de mandataire
☒ Beschreibung / Description	3	☐ Prioritätsdokument(e) / Priority document(s) / Document(s) de priorité
☒ Ansprüche / Claim(s) / Revendication(s)	3	☐ Scheck / Cheque / Chèque
☒ Zeichnung(en) / Drawing(s) / Dessin(s)	3	☐ Antrag zur Belastung des laufendes Konto / Request to charge deposit account / Demande de débit de compte-courant
☒ Zusammenfassung / Abstract / Abrégé	3	☐ Andere Unterlagen / Other Documents / Autres documents

Die genannten Unterlagen sind am obengenannten Tag eingegangen; die Anmeldung hat die ebenfalls oben angeführte Anmeldenummer erhalten.

The said items were received on the date indicated above and the application has been assigned the above indicated application number.

Les documents mentionnés ont été reçus à la date indiquée ci-dessus et le numéro de demande de brevet indiqué ci-dessus a été attribué à la demande.

EUROPÄISCHES PATENTAMT DEN HAAG 228 EUROPEAN PATENT OFFICE LA HAYE OFFICE EUROPEEN DES BREVETS

Unterschrift/Amtsstempel
Signature/Official Stamp
Signature/Cachet officiel

René De Hoogd

Form PCT/RO/1030/02.91 - P20401

Atty. Docket No. KIL01 P-424
Express Mail No EL545347964US

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

PCT/EP 0 1 / 0 0 8 1 7
International Application No.

25 JAN 2001 (25. 01. 01)
International Filing Date

EUROPEAN PATENT OFFICE
PCT INTERNATIONAL APPLICATION
Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* JLWM/P31175WO

Box No. I TITLE OF INVENTION

MEDICAL DEVICE AND LOCKING MECHANISM THEREFOR

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Nicodel S.A.
10 Rue St. Pierre
CP447-1701 Fribourg
Switzerland

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(that is, country)* of nationality: Switzerland

State *(that is, country)* of residence: Switzerland

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

MASTORAKIS, Emmanuel
10 Rue St. Pierre
CP447-1701 Fribourg
Switzerland

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: Greece

State *(that is, country)* of residence: Monaco

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

Miller; James Lionel Woolverton
Kilburn & Strode
20 Red Lion Street
London WC1R 4PJ
United Kingdom

Telephone No. 020 7539 4200

Facsimile No. 020 7539 4299

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

See Notes to the request form

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

☒ **AP** **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT

☒ **EA** **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ **EP** **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, TR Turkey, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ **OA** **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒ **AE** United Arab Emirates
☒ **AG** Antigua and Barbuda
☒ **AL** Albania .....
☒ **AM** Armenia .....
☒ **AT** Austria .....
☒ **AU** Australia .....
☒ **AZ** Azerbaijan
☒ **BA** Bosnia and Herzegovina .....
☒ **BB** Barbados
☒ **BG** Bulgaria .....
☒ **BR** Brazil .....
☒ **BY** Belarus .....
☒ **BZ** Belize .....
☒ **CA** Canada
☒ **CH and LI** Switzerland and Liechtenstein
☒ **CN** China .....
☒ **CR** Costa Rica .....
☒ **CU** Cuba .....
☒ **CZ** Czech Republic .....
☒ **DE** Germany .....
☒ **DK** Denmark .....
☒ **DM** Dominica
☒ **DZ** Algeria .....
☒ **EE** Estonia .....
☒ **ES** Spain .....
☒ **FI** Finland .....
☒ **GB** United Kingdom
☒ **GD** Grenada
☒ **GE** Georgia .....
☒ **GH** Ghana .....
☒ **GM** Gambia
☒ **HR** Croatia .....
☒ **HU** Hungary .....
☒ **ID** Indonesia
☒ **IL** Israel .....
☒ **IN** India .....
☒ **IS** Iceland
☒ **JP** Japan .....
☒ **KE** Kenya .....
☒ **KG** Kyrgyzstan .....
☒ **KP** Democratic People's Republic of Korea .....
☒ **KR** Republic of Korea .....
☒ **KZ** Kazakhstan .....
☒ **LC** Saint Lucia
☒ **LK** Sri Lanka
☒ **LR** Liberia
☒ **LS** Lesotho .....
☒ **LT** Lithuania
☒ **LU** Luxembourg
☒ **LV** Latvia
☒ **MA** Morocco .....
☒ **MD** Republic of Moldova .....
☒ **MG** Madagascar .....
☒ **MK** The former Yugoslav Republic of Macedonia .....
☒ **MN** Mongolia
☒ **MW** Malawi .....
☒ **MX** Mexico .....
☒ **MZ** Mozambique
☒ **NO** Norway
☒ **NZ** New Zealand .....
☒ **PL** Poland .....
☒ **PT** Portugal .....
☒ **RO** Romania
☒ **RU** Russian Federation .....
☒ **SD** Sudan
☒ **SE** Sweden
☒ **SG** Singapore
☒ **SI** Slovenia .....
☒ **SK** Slovakia .....
☒ **SL** Sierra Leone .....
☒ **TJ** Tajikistan .....
☒ **TM** Turkmenistan .....
☒ **TR** Turkey .....
☒ **TT** Trinidad and Tobago .....
☒ **TZ** United Republic of Tanzania
☒ **UA** Ukraine .....
☒ **UG** Uganda .....
☒ **US** United States of America .....
☒ **UZ** Uzbekistan .....
☒ **VN** Viet Nam .....
☒ **YU** Yugoslavia .....
☒ **ZA** South Africa .....
☒ **ZW** Zimbabwe .....

Check-box reserved for designating States which have become party to the PCT after issuance of this sheet:

☐ .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Supplemental Box *If the Supplemental Box is not used, this sheet should not be included in the request.*

1. If, in any of the Boxes, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:

*(i) **if more than two persons are involved as applicants and/or inventors** and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;*

*(ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication **"the States indicated in the Supplemental Box"** is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;*

*(iii) if, in Box No. II or in any of the sub-boxes of Box No. III, **the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America**: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;*

*(iv) if, in addition to the agent(s) indicated in Box No. IV, there are **further agents**: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;*

*(v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "**patent of addition**," or "**certificate of addition**," or if, in Box No. V, the name of the United States of America is accompanied by an indication "**continuation**" or "**continuation-in-part**": in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;*

*(vi) if, in Box No. VI, there are **more than three earlier applications whose priority is claimed**: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI;*

*(vii) if, in Box No. VI, **the earlier application is an ARIPO application**: in such case, write "Continuation of Box No. VI", specify the number of the item corresponding to that earlier application and indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed.*

*2. If, with regard to the **precautionary designation statement** contained in Box No. V, the applicant wishes to exclude any State(s) from the scope of that statement: in such case, write "Designation(s) excluded from precautionary designation statement" and indicate the name or two-letter code of each State so excluded.*

*3. If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerning **non-prejudicial disclosures or exceptions to lack of novelty**: in such case, write "Statement concerning non-prejudicial disclosures or exceptions to lack of novelty" and furnish that statement below.*

Additional Representatives:

KEARNEY,	Kevin David Nicholas
ASHMEAD,	Richard John
JENNINGS,	Nigel Robin
REES,	David Christopher
MAGGS,	Michael Norman
HALE,	Peter
CHAPMAN,	Paul William
MILLER,	James Lionel Woolverton
ROBERTS,	Gwilym Vaughan
CORNISH,	Kristina Victoria Joy
KINSLER,	Maureen Catherine
LEE,	Nicholas John
FLORENCE,	Julia Anne
BASSIL,	Nicholas Charles
SHAH,	Punita
COPSEY,	Timothy Graham

All of:

Kilburn & Strode
20 Red Lion Street
London WC1R 4PJ
United Kingdom

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) 22 December 2000 (22-12-2000)	20000100459	Greece		
item (2)				
item (3)				

☐ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): _____

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)* :

ISA / EPO

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets:**

request	:	4
description (excluding sequence listing part)	:	20
claims	:	9
abstract	:	1
drawings	:	6
sequence listing part of description	:	
Total number of sheets	:	40

This international application is **accompanied by** the item(s) marked below:

1. ☒ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☑ other *(specify)*: Letter

Figure of the drawings which should accompany the abstract: 1

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

MILLER; James Lionel Woolverton
Authorised Representative

23/1/01

For receiving Office use only

1. Date of actual receipt of the purported international application: 25.01.01 — 25 JAN 2001
2. Drawings: ☒ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA /
6. ☒ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

Atty. Docket No. KIL01 P-424
Express Mail No. EL545347964US

PCT

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s):
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Nicodel S.A.
10 Rue St. Pierre
CP447-1701 Fribourg
Switzerland

MASTORAKIS, Emmanuel
10 Rue St. Pierre
CP447-1701 Fribourg
Switzerland

hereby appoint(s) the following person as: ☒ agent ☐ common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

KEARNEY, Kevin David Nicholas; ASHMEAD, Richard John; JENNINGS, Nigel Robin; REES, David Christopher; MAGGS, Michael Norman; HALE, Peter; CHAPMAN, Paul William; MILLER, James Lionel Woolverton; ROBERTS, Gwilym Vaughan; CORNISH, Kristina Victoria Joy; KINSLER, Maureen Catherine; FLORENCE, Julia Anne; LEE, Nicholas John; BASSIL, Nicholas Charles; SHAH, Punita; COPSEY, Timothy Graham

All of: Kilburn & Strode
20 Red Lion Street
London WC1R 4PJ
United Kingdom

to represent the undersigned before

☒ all the competent International Authorities
☐ the International Searching Authority only
☐ the International Preliminary Examining Authority only

in connection with any and all international applications filed by the undersigned with the following Office

European Patent Office as receiving Office

and to make or receive payments on behalf of the undersigned.

Signature(s) *(where there are several persons, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading this power):*

D de Faria e Castro

DIRECTOR
NICODEL SA

Date: 26.01.01

Emmanuel Mastorakis

Date: 6. FEB 2001

Form PCT/Model of general power of attorney (for several international applications) (July 1992)

Atty. Docket No. KIL01 P-424
Express Mail No EL545347964US

PATENT COOPERATION TREATY

From the RECEIVING OFFICE

PCT

To:
Miller, J.L.W.
KILBURN & STRODE
20 Red Lion Street
London WC1R 4PJ
GRANDE BRETAGNE

NOTIFICATION OF THE INTERNATIONAL APPLICATION NUMBER AND OF THE INTERNATIONAL FILING DATE

(PCT Rule 20.5(c))

Date of mailing *(day/month/year)*	09 FEB 2001
Applicant's or agent's file reference: JLWM/P31175WO	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 01/00817	25/01/2001	22/12/2000

Applicant: NICODEL S.A.

Title of the invention:

1. The applicant is hereby notified that the international application has been accorded the international application number and the international filing date indicated above.
2. The applicant is further notified that the record copy of the international application was transmitted to the International Bureau on the above date of mailing.
3. ☐ Other:

* The International Bureau monitors the transmittal of the record copy by the receiving Office and will notify the applicant (with Form PCT/IB/301) of its receipt. Should the record copy not have been received by the expiration of 14 months from the priority date, the International Bureau will notify the applicant (Rule 22.1(c)).

Name and mailing address of the receiving Office	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mrs. H. Fransz

Form PCT/RO/105 (0792) P20402

10069.688

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
JLWM/P31175WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 01/00817	25/01/2001	22/12/2000
Applicant		
NICODEL S.A.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [X] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1a, 4c

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [X] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 01/00817

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 50, 51, 52
because they relate to subject matter not required to be searched by this Authority, namely:

PCT Rule 6.2(a)

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-15, 16-22, 37, 38-42, 45-47

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-15, 16-22, 37 (when dependent of claims 16-22), 38-42 and 45-47 (when dependent of claims 1-22)

locking mechanism for controling engagement between parts movable relative to one another in medical sharp devices having
claim 1: retainer part with first formation, second formation located on a body part of the sharp device and connector part to alter relative engagement between the first and second formations;
claim 16: retainer part including connector portion, connector part;

2. Claims: 23-25, 38-42 and 45-47 (when dependent of claims 23-25), 48,49

hypodermic needle assembly having a needle, retainer with elongate bore, push-fit between needle and bore;

3. Claims: 26-42, 37 (when dependent of claims 23-36)

hypodermic needle assembly having a fluid container, main body with shoulder, cylindrical neck portion and open front end, needle retainer being removabely insertable through the open front end of the neck portion and having needle retainer and needle;

4. Claims: 43, 44, 53-56

claim 43: medical device having a syringe with an eccentrically located neck portion and an eccentrically located connector part located on a plunger;
claim 53: syringe device having a barrel portion, plunger, barrel portion having an eccentrically located neck, means for preventing rotation of plunger in a barrel.

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]/EP 01/00817

A. CLASSIFICATION OF SUBJECT MAT[redacted]
IPC 7 A61M5/50 A61M5/32 A61M5/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 718 358 A (MERCHIN CHARLES;ELFANDI PATRICE) 13 October 1995 (1995-10-13) page 7, line 24 -page 8, line 7 page 8, line 33 - line 35 page 9, line 34 -page 10, line 20 figures	1-5, 8-11, 16-18, 20-22, 37-39, 42,47
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A	---	3,12,21, 22
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
21 August 2001	26. 03. 2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	SEDY R.

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INTERNATIONAL SEARCH REPORT

International Application No
[redacted]T/EP 01/00817

C.(Continuation) DOCUMENTS CONSIDE[redacted]D TO BE RELEVANT

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A		2-5,8, 11-13, 45,46

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